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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,092	07/12/2007	Kirk Knowlton	ST-UCSD3120-1	7890

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,092	KNOWLTON ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/19/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 2/11/10 wherein the specification was amended; claims 1-6 and 14-30 were canceled; and claims 7 and 8 were amended.

Note: Claims 7-13 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 2/11/10 to the rejection of claims 7-13, 20-26, 28, and 30 made by the Examiner under 35 USC 102, 103, and/or 112 have been fully considered and deemed persuasive because Applicant has amended and/or canceled the appropriate claims. Therefore, the said rejections are hereby withdrawn.

NEW GROUNDS OF REJECTIONS

102 Rejection

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Badorff et al (Nature Medicine, 1999, Vol. 5, No. 3, pages 320-326).

Badorff et al disclose that the enteroviral protease 2A cleaves dystrophin. Enteroviruses (i.e., Coxsackievirus B3) causes dilated cardiomyopathy. In the studies of Badorff et al, it was illustrated that purified Coxsackievirus protease 2A cleaves

dystrophin *in vitro* and dystrophin is also cleaved during Coxsackievirus infection of cultured myocytes and in infected mouse hearts. *In vivo*, dystrophin and the dystrophin-associated gycoproteins are morphologically disrupted in infected myocytes. Badorff et al conclude that enteroviral infection contributes to the pathogenesis of acquired forms of dilated cardiomyopathy (see entire document, especially, abstract; page 320, left and right column, bridging paragraph; page 320; right column, first and second complete paragraphs; pages 320-321, bridging paragraph; page 322, Figure 2; page 323, Figures 3 and 4; page 324, Figure 5; 324-325, bridging paragraph; page 325, entire page). In addition, Badorff et al discloses the following: (1) the cleavage of dystrophin by Coxsackievirus protease 2A (page 321, Figure 1). (2) Coxsackieviral protease 2A cleaves dystrophin at residues 588 and 2434 (page 321, left column, first complete paragraph). (3) Protein extracts were cultured from rat neonatal ventricular myocytes and analyzed by western blot using an antibody against dystrophin, Dy4/6D3, that recognizes the rod domain of dystrophin. The cleavage of human dystrophin in heart extracts by purified protease 2A resulted in two dystrophin fragments (residues 588 and 2434) [page 321, left and right columns, bridging paragraphs). (4) Badorff et al disclose that dystrophin function is impaired during Coxsackievirus B3 infection of cardiac myocytes (pages 321-322, bridging paragraph; page 322, left column, third and fourth complete paragraph). (5) In Vivo studies were conducted to determine if enterovirus-mediated cleavage of dystrophin can occur in intact heart. Mice studies were performed and data obtained after seven days. The in vivo data was consistent with data obtained in vitro (page 322, right column, first complete paragraph). (6) Dystrophin

immunostaining in infected myocytes in the intact hearts with an antibody against Coxsackievirus B3 and the antibody against dystrophin indicated that dystrophin staining was disrupted in all hearts of most Coxsackievirus B3 infected cells (page 322, right column, second complete paragraph). (7) Evans staining was also performed and data indicated that many myocytes that stained positive for Evans blue dye was in infected hearts (pages 322-323, bridging paragraph). (8) Badorff et al disclose the procedures for performing their experiments. The experimental method includes disclosure regarding the viruses, mice, myocyte culture and heart tissue, antibodies, Western blots, protease 2A cleavage assay, and immunofluorescence procedure (page 325, entire page).

Thus, both Applicant and Badorff et al disclose a method of immunologically detecting an enteroviral infection in a subject's heart wherein the method involves in vitro immunological detection of a dystrophin cleavage product produced by enteroviral protease 2A cleavage.

CLARIFICATION OF THE RECORD

5. It should be noted that elected Group II is directed to a method (and kit thereof) for detecting an enteroviral infection in vitro as set forth in pending claims 7-13.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor,

Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

May 20, 2010